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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,361	07/18/2000	Ambikaipakan Balasubramaniam	UOC/136R	8955

7590 07/16/2002  
Wood Herron & Evans LLP  
2700 Carew Tower  
Cincinnati, OH 45202

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/16/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/618,361

Applicant(s)

BALASUBRAMANIAM ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-11, 16, 17 and 25-52 is/are pending in the application.
- 4a) Of the above claim(s) 3-11, 16, 17 and 25-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Please note the serial no. of this application is 09/618,361, not 09/628,326, both the response filed on April 15, 2002 and CRF use the wrong serial no. 09/628,326. The continuation data of this application at page 1 of the specification has been entered.

#### ***Status of the Claims***

2. Claims 3-11, 16-17, 25-52 are pending.

Applicants' amendment filed on April 15, 2002 (Paper No. 5) is acknowledged, and applicants' response has been fully considered. Claims 1, 2, 12-15 and 18-24 have been cancelled, new claims 40-52 have been added. Claims 3-11, 16, 17 and 25-39 are non-elected inventions and withdrawn from consideration. Thus, claims 40-52 are examined.

#### ***Sequence Listing***

3. The amendment to the specification regarding addition of the "SEQ ID NO:" for amino acid sequences is entered. However, the CRF submitted by applicants has error (see attached raw sequence listing error report). Appropriate correction is required. Applicants must comply with the requirements of the sequence rules (37 CFR 1.81-1.825) and provide a copy of sequence listing and CRF containing all the sequences.

#### ***Abstract***

4. Please delete the phrase "Background of the Invention" at page 58 of abstract.

#### ***Drawing***

5. A new set of drawing submitted by the applicant is acknowledged.

#### **Objection Withdrawn**

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6. The previous objection to claims 1 and 21 regarding the use of brackets ([..]) and the term "t.Bu" or "being is", is withdrawn in view of applicants cancellation of the claim, and making corrections in the claims.

**Rejection Withdrawn**

***Claim Rejections-Obviousness Type Double Patenting***

7. The previous rejection of claims 1, 2 and 13-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent 6,235,718, is withdrawn in view of applicants' submission of a terminal disclaimer (Paper No. 6), applicants' cancellation of the claim, and applicants' response at page 9 in paper No. 5.

8. The previous rejection of claims 12 and 18-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent 6,235,718 in view of Domen *et al.* (WO 91/03494), Spindel *et al.* (U. S. Patent 5,410,018) or Sakurada *et al.* (U. S. Patent 5,993,843), is withdrawn in view of applicants' submission of a terminal disclaimer (Paper No. 6), applicants' cancellation of the claim, and applicants' response at page 9 in paper No. 5.

***Claim Rejections - 35 USC § 112***

9. The previous rejection of claims 1, 12-15 and 18-24, under 35 U.S.C.112, second paragraph, regarding the term "e. g.", "Dap", "Pyr", "Tip", "etc.", "amino acid derivatives", "to a subject in need of said compound", "capable of" and "NPY", or including the non-elected sequences, is withdrawn in view of applicants' cancellation to the claim, applicants' amendment to the specification to include the chemical name, and applicants' response at pages 9-12 in Paper No. 5.

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***Claim objection***

10. Claim 40 is objected to because of the use of the terms "CaMe-Trp", "CaMe-Gln", "N-Me-Arg", and "Lys-e-NH-R". The position of the substituent ( $\alpha$  or  $\epsilon$ ) should be indicated in the term, e.g., C $\alpha$ Me-Trp, N $\alpha$ -Me-Arg or N $\epsilon$ (R)-Lys.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 40-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-52 are indefinite because of the use of the term "each bond between two amino acids, represented by a dash"-", can be either a peptide bond or a pseudopeptide bond or a pharmaceutically acceptable salt" or "any Trp derivative". The term "each bond between two amino acids, represented by a dash"-", can be either a peptide bond or a pseudopeptide bond or a pharmaceutically acceptable salt" or "any Trp derivative" renders the claim indefinite, it is not clear how a bond between two amino acids can be a pharmaceutically acceptable salt, what compounds are intended as "Trp derivative", and how different the Trp derivative is as compared to the parent compound, Trp. Claims 41-53 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the specification has shown the derivatives of Trp (page 9, line 15 and page 13, line 20; page 10 of the response). The argument is not found persuasive

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because the specification only indicates two Trp derivatives, 2-chloro and Tcc derivatives, while the claim encompasses any Trp derivative, it is not clear which compound is the "any Trp derivative".

12. Claim 43 recites the limitation "amino acid derivatives" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Koenig *et al.* (EP 288965 (November, 1988)).

Koenig *et al.* teach a peptide having formula of L-B-A, wherein L is lipophilic residue, B is basic residue, A is aromatic residue and C-terminal carboxyl group is protected as an ester or amide, is useful as Phospholipase A2 inhibitor. For example, Z-Trp-Lys-Tyr-OMe (compound no. 2, page 4), Z-Trp-Lys-Tyr-NH<sub>2</sub> (compound no. 3), Ac-Trp-Lys-Trp-NH-(CH<sub>2</sub>)<sub>4</sub>CH<sub>3</sub> (compound no. 14), Z-Trp-Lys-Tyr-benzylamide (compound no. 40), Z-Trp-Lys-Tyr-phenethylamide (compound no. 41), Z-Trp-Lys-Tic-NH<sub>2</sub> (compound no. 43), are included in claim 40 of the instant application, thus meets the criteria of claim 40.

In response, applicants indicate Koenig *et al.* teach a lysine residue is contained in all the compounds cited by the Examiner, while the claim does not show a lysine being selected as A2 position (pages 11-12 of the response). The argument is not found persuasive because the claim

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recites A2 being Lys-e-NH-R, where R can be hydrogen, which is the lysine residue. Therefore, the compound in claim 40 is anticipated by Koenig *et al.*

**Conclusion**

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

*Christopher S. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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July 11, 2002